

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

[mark one]

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2023

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 1-36598

CELLECTAR BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

04-3321804
(IRS Employer
Identification No.)

100 Campus Drive
Florham Park, New Jersey 07932
(Address of principal executive offices, including zip code)

(608) 441-8120
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common stock, par value \$0.00001	CLRB	NASDAQ Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares outstanding of the issuer's common stock as of the latest practicable date: 12,288,325 shares of common stock, \$0.00001 par value per share, as of November 10, 2023.

CELLECTAR BIOSCIENCES, INC.

FORM 10-Q INDEX

Forward-Looking Statements	3
PART I. FINANCIAL INFORMATION	5
Item 1. Financial Statements	5
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 4. Controls and Procedures	27
PART II. OTHER INFORMATION	29
Item 1. Legal Proceedings	29
Item 1A. Risk Factors	29
Item 6. Exhibits	30

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q of Collectar Biosciences, Inc. (the “Company”, “Collectar”, “we”, “us”, “our”) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. Examples of our forward-looking statements include:

- our current views with respect to our business strategy, business plan and research and development activities;
- the progress of our product development programs, including clinical testing and the timing of commencement and results thereof;
- our projected operating results, including research and development expenses;
- our ability to continue development plans for iopofosine I 131 (also known as CLR 131), CLR 1900 series, CLR 2000 series and CLR 12120;
- our ability to continue development plans for our Phospholipid Drug Conjugates (PDC)TM;
- our ability to maintain orphan drug designation in the U.S. for iopofosine as a therapeutic for the treatment of multiple myeloma, neuroblastoma, osteosarcoma, rhabdomyosarcoma, Ewing’s sarcoma and lymphoplasmacytic lymphoma, and the expected benefits of orphan drug status;
- any disruptions at our sole supplier of iopofosine;
- our ability to pursue strategic alternatives;
- our ability to advance our technologies into product candidates;
- our enhancement and consumption of current resources along with ability to obtain additional funding;
- our current view regarding general economic and market conditions, including our competitive strengths;
- uncertainty and economic instability resulting from conflicts, military actions, terrorist attacks, natural disasters, public health crises, including the occurrence of a contagious disease or illness such as the COVID-19 pandemic, cyber-attacks and general instability;
- the future impacts of legislative and regulatory developments in the United States on the pricing and reimbursement of our product candidates;
- our ability to meet the continued listing standards of Nasdaq;
- assumptions underlying any of the foregoing; and
- any other statements that address events or developments that we intend or believe will or may occur in the future.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should,” “could,” “would,” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Forward-looking statements also involve risks and uncertainties, many of which are beyond our control. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this quarterly report.

You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this report is accurate as of the date hereof only. Because the risk factors referred to herein could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking

[Table of Contents](#)

statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

This quarterly report on Form 10-Q contains trademarks and service marks of Collectar Biosciences, Inc. Unless otherwise provided in this quarterly report on Form 10-Q, trademarks identified by TM are trademarks of Collectar Biosciences, Inc. All other trademarks are the property of their respective owners.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 18,986,443	\$ 19,866,358
Prepaid expenses and other current assets	1,123,467	663,243
Total current assets	20,109,910	20,529,601
Fixed assets, net	893,509	418,641
Right-of-use asset, net	517,566	560,334
Long-term assets	23,566	75,000
Other assets	6,214	6,214
TOTAL ASSETS	\$ 21,550,765	\$ 21,589,790
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued liabilities	\$ 7,814,590	\$ 5,478,443
Warrant liability	8,600,000	—
Lease liability	56,263	50,847
Total current liabilities	16,470,853	5,529,290
Long-term lease liability, net of current portion	512,750	552,981
TOTAL LIABILITIES	16,983,603	6,082,271
COMMITMENTS AND CONTINGENCIES (Note 7)		
MEZZANINE EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series E-1 preferred stock: 1,225 issued and outstanding as of September 30, 2023, and none as of December 31, 2022 (Note 3)	17,920,000	—
STOCKHOLDERS' (DEFICIT) EQUITY:		
Preferred stock, \$0.00001 par value; 7,000 shares authorized; Series D preferred stock: 111 issued and outstanding as of September 30, 2023, and December 31, 2022	1,382,023	1,382,023
Common stock, \$0.00001 par value; 160,000,000 shares authorized; 9,918,384 and 9,385,272 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	99	94
Additional paid-in capital	195,298,922	193,624,445
Accumulated deficit	(210,033,882)	(179,499,043)
Total stockholders' (deficit) equity	(13,352,838)	15,507,519
TOTAL LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' (DEFICIT) EQUITY	\$ 21,550,765	\$ 21,589,790

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
COSTS AND EXPENSES:				
Research and development	\$ 7,312,504	\$ 5,380,190	\$ 20,275,004	\$ 13,765,846
General and administrative	2,100,956	2,435,296	6,137,760	7,625,391
Total costs and expenses	<u>9,413,460</u>	<u>7,815,486</u>	<u>26,412,764</u>	<u>21,391,237</u>
LOSS FROM OPERATIONS	<u>(9,413,460)</u>	<u>(7,815,486)</u>	<u>(26,412,764)</u>	<u>(21,391,237)</u>
OTHER (EXPENSE) INCOME:				
Warrant issuance expense	(470,000)	—	(470,000)	—
Loss on revaluation of warrants	(3,900,000)	—	(3,900,000)	—
Interest income, net	51,110	4,164	247,925	5,075
Total other income	<u>(4,318,890)</u>	<u>4,164</u>	<u>(4,122,075)</u>	<u>5,075</u>
NET LOSS	<u>\$ (13,732,350)</u>	<u>\$ (7,811,322)</u>	<u>\$ (30,534,839)</u>	<u>\$ (21,386,162)</u>
BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE				
	<u>\$ (1.21)</u>	<u>\$ (1.28)</u>	<u>\$ (2.71)</u>	<u>\$ (3.50)</u>
SHARES USED IN COMPUTING BASIC AND DILUTED NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS PER COMMON SHARE				
	<u>11,308,738</u>	<u>6,110,119</u>	<u>11,277,231</u>	<u>6,110,123</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY
(Unaudited)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Par Amount			
BALANCE AT DECEMBER 31, 2021	111	\$ 1,382,023	6,110,126	\$ 61	\$ 182,560,859	\$ (150,897,789)	\$ 33,045,154
Stock-based compensation	—	—	—	—	303,805	—	303,805
Net loss	—	—	(1)	—	—	(6,139,797)	(6,139,797)
BALANCE AT MARCH 31, 2022	111	\$ 1,382,023	6,110,125	\$ 61	\$ 182,864,664	\$ (157,037,586)	\$ 27,209,162
Stock-based compensation	—	—	—	—	419,953	—	419,953
Retired Shares	—	—	(2)	—	—	—	—
Net loss	—	—	—	—	—	(7,435,043)	(7,435,043)
BALANCE AT JUNE 30, 2022	111	\$ 1,382,023	6,110,123	\$ 61	\$ 183,284,617	\$ (164,472,629)	\$ 20,194,072
Stock-based compensation	—	—	—	—	367,759	—	367,759
Retired Shares	—	—	(4)	—	—	—	—
Net loss	—	—	—	—	—	(7,811,322)	(7,811,322)
BALANCE AT SEPTEMBER 30, 2022	111	\$ 1,382,023	6,110,119	\$ 61	\$ 183,652,376	\$ (172,283,951)	\$ 12,750,509
BALANCE AT DECEMBER 31, 2022	111	\$ 1,382,023	9,385,272	\$ 94	\$ 193,624,445	\$ (179,499,043)	\$ 15,507,519
Stock-based compensation	—	—	—	—	408,206	—	408,206
Conversion of pre-funded warrants into common shares	—	—	355,235	3	—	—	3
Net loss	—	—	—	—	—	(8,581,267)	(8,581,267)
BALANCE AT MARCH 31, 2023	111	\$ 1,382,023	9,740,507	\$ 97	\$ 194,032,651	\$ (188,080,310)	\$ 7,334,461
Stock-based compensation	—	—	—	—	419,757	—	419,757
Net loss	—	—	—	—	—	(8,221,222)	(8,221,222)
BALANCE AT JUNE 30, 2023	111	\$ 1,382,023	9,740,507	\$ 97	\$ 194,452,408	\$ (196,301,532)	\$ (467,004)
Stock-based compensation	—	—	—	—	497,878	—	497,878
Exercise of warrants into common shares	—	—	177,877	2	348,636	—	348,638
Net loss	—	—	—	—	—	(13,732,350)	(13,732,350)
BALANCE AT SEPTEMBER 30, 2023	111	\$ 1,382,023	9,918,384	\$ 99	\$ 195,298,922	\$ (210,033,882)	\$ (13,352,838)

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	Nine Months Ended	
	September 30,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (30,534,839)	\$ (21,386,162)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	122,415	110,276
Stock-based compensation expense	1,325,841	1,091,517
Noncash lease expense	42,768	66,547
Loss on disposal of fixed assets	—	3,386
Warrant issuance expense	470,000	—
Loss on revaluation of warrants	3,900,000	—
Changes in:		
Prepaid expenses and other current assets	(408,790)	(108,451)
Lease liability	(34,815)	(99,772)
Accounts payable and accrued liabilities	2,336,146	2,512,121
Cash used in operating activities	<u>(22,781,274)</u>	<u>(17,810,538)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of fixed assets	(597,282)	(108,115)
Cash used in investing activities	<u>(597,282)</u>	<u>(108,115)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	348,641	—
Proceeds from issuance of preferred stock and warrants, net of issuance costs	22,150,000	—
Cash provided by financing activities	<u>22,498,641</u>	<u>—</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	(879,915)	(17,918,653)
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,866,358	35,703,975
CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$ 18,986,443	\$ 17,785,322

The accompanying notes are an integral part of these condensed consolidated financial statements.

CELLECTAR BIOSCIENCES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. NATURE OF BUSINESS AND ORGANIZATION

Cellectar Biosciences, Inc. (the Company, our, we) is a late-stage clinical biopharmaceutical company focused on the discovery and development of drugs for the treatment of cancer leveraging our proprietary phospholipid drug conjugate™ (PDC™) delivery platform that specifically targets cancer cells and delivers improved efficacy and better safety as a result of fewer off-target effects.

The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated deficit of approximately \$210,034,000 as of September 30, 2023. During the nine months ended September 30, 2023, the Company generated a net loss of approximately \$30,535,000, and the Company expects that it will continue to generate operating losses for the foreseeable future. The Company believes that its cash balance as of September 30, 2023, is adequate to fund its basic budgeted operations into the second quarter of 2024. The Company's ability to execute its current operating plan depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives, but there can be no assurance that it will obtain the necessary funding, raising substantial doubt about the Company's ability to continue as a going concern within one year of the date these financial statements are issued. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The condensed consolidated financial statements have been prepared by Cellectar Biosciences, Inc. in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. Management believes the disclosures made in this document are adequate with respect to interim reporting requirements.

The accompanying unaudited condensed consolidated financial statements, taken as a whole, contain all adjustments that are of a normal recurring nature necessary to present fairly the operating results, cash flows, and financial position of the Company as of and for the period ended September 30, 2023. The accompanying condensed consolidated balance sheet as of December 31, 2022 has been derived from our audited financial statements. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related notes thereto included in the Company's Form 10-K for the fiscal year ended December 31, 2022, which was filed with the SEC on March 9, 2023.

Principles of Consolidation — The consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates — The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Significant estimates include the assumptions used in the accrual for potential liabilities, the valuation of the warrant liability, the valuation of debt and equity instruments, the valuation of stock options issued for services, and deferred tax valuation allowances. Actual results could differ from those estimates.

Fixed Assets — Property and equipment are stated at cost. Depreciation on property and equipment is provided using the straight-line method over the estimated useful lives of the assets (3 to 10 years). Because of the significant value of leasehold improvements purchased, leasehold improvements are depreciated over 64 months (their estimated useful life), which represents the full term of the lease at the time the leasehold improvements were capitalized. Our only long-lived assets are property and equipment. The Company periodically evaluates long-lived assets for potential impairment. Whenever events or circumstances change, an assessment is made as to whether there has been impairment to the value of long-lived assets by determining whether projected undiscounted cash flows

[Table of Contents](#)

generated by the applicable asset exceed its net book value as of the assessment date. There were no long-lived fixed asset impairment charges recorded during the nine months ended September 30, 2023.

Right-of-Use (ROU) Asset and Lease Liabilities -The Company accounts for all material leases in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 842, *Leases*. ROU Assets are amortized over their estimated useful life, which represents the full term of the lease.

Stock-Based Compensation — The Company uses the Black-Scholes option-pricing model to calculate the grant-date fair value of stock option awards. The resulting compensation expense for awards that are not performance-based is recognized on a straight-line basis over the service period of the award, which for stock option grants issued in 2023 and 2022 ranged from one year to three years.

Research and Development — Research and development costs are expensed as incurred. The Company recognizes revenue and cost reimbursements from government grants when it is probable that the Company will comply with the conditions attached to the grant arrangement and the grant proceeds will be received. Government grants are recognized in the Condensed Consolidated Statements of Operations on a systematic basis over the periods in which the Company recognizes the related costs for which the government grant is intended to compensate. Specifically, when government grants are related to reimbursements for cost of revenues or operating expenses, the government grants are recognized as a reduction of the related expense in the Condensed Consolidated Statements of Operations. The Company records government grants receivable in the Condensed Consolidated Balance Sheets in prepaid expenses and other current assets.

Income Taxes — Income taxes are accounted for using the liability method of accounting. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized. Management has provided a full valuation allowance against the Company's gross deferred tax asset. Tax positions taken or expected to be taken in the course of preparing tax returns are required to be evaluated to determine whether the tax positions are "more likely than not" to be sustained by the applicable tax authority. Tax positions deemed not to meet a more-likely-than-not threshold would be recorded as tax expense in the current year. There are no uncertain tax positions that require accrual to or disclosure in the financial statements as of September 30, 2023 and December 31, 2022.

Fair Value of Financial Instruments — The guidance under FASB ASC Topic 825, *Financial Instruments*, requires disclosure of the fair value of certain financial instruments. Financial instruments in the accompanying financial statements consist of cash equivalents, prepaid expenses and other assets, accounts payable, warrant liabilities, and long-term obligations. The carrying amount of cash equivalents, prepaid expenses, other current assets, and accounts payable approximate their fair value as a result of their short-term nature. (See Note 2)

Warrants — The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Valuation changes, as well as the cost to issue the warrants, are included in Other (Expense) Income in the accompanying Condensed Consolidated Statements of Operations. If these instruments are initially classified as liabilities and subsequently meet the requirements for equity classification, the Company reclassifies the fair value to equity.

Preferred Stock — The Company accounts for preferred stock based upon their specific terms and the authoritative guidance in ASC 480 and ASC 815, including whether they are freestanding instruments, whether any redemption or conversion aspects exist and how they are required to be settled (particularly if there is a cash settlement aspect), whether they contain characteristics that are predominantly debt-like or equity-like, whether they have embedded derivatives, and if they have redemption features. Based upon analysis of these criteria, the preferred stock will be classified as either debt, temporary (or "mezzanine") equity, or permanent equity. The resultant classification is then evaluated quarterly to determine whether any change to the classification is required.

Concentration of Credit Risk — Financial instruments that subject the Company to credit risk consist of cash and cash equivalents on deposit with financial institutions. The Company's excess cash as of September 30, 2023 and December 31, 2022 is on deposit in interest-bearing accounts with well-established financial institutions. At times, such amounts may exceed the FDIC insurance limits. As of September 30, 2023, and December 31, 2022, uninsured cash balances totaled approximately \$18,486,000 and \$19,400,000, respectively.

Recently Adopted Accounting Pronouncements — For the fiscal year beginning January 1, 2022, management adopted ASU 2021-10, Government Assistance (Topic 832), which aims to provide increased transparency by requiring business entities to disclose information about certain type of government assistance they receive in the notes to the financial statements. Reimbursements of eligible expenditures pursuant to government assistance programs are recorded as reductions of operating costs when there is reasonable assurance that the Company will comply with the conditions attached to the grant arrangement and when the reimbursement has been claimed. The determination of the amount of the claim, and accordingly the receivable amount, requires management to make calculations based on its interpretation of eligible expenditures in accordance with the terms of the programs. The reimbursement claims submitted by the Company are subject to review by the relevant government agencies. The Company currently has a cancer treatment research award through the National Cancer Institute (NCI) totaling approximately \$2.0 million over a period of approximately three years. In September 2022, we were awarded \$1.98 million in additional grant funding to expand our ongoing Phase 1 study of iopofosine I 131 in children and adolescents with inoperable relapsed or refractory high grade gliomas (HGGs). The grant was awarded by the NCI based upon the initial signals of efficacy in the Phase 1 study, which is an international, open-label, dose escalation, safety study. The funding allows for an expansion from Part 1a into the Part 1b portion of our ongoing Phase 1 pediatric study.

During the three months ended September 30, 2023, the Company received approximately \$667,000 in NCI grant funding under the grants described above, all of which was reported as a reduction of research and development (R&D) expenses. During the nine months ended September 30, 2023, the Company received approximately \$1,314,000 in NCI grants, all of which was reported as a reduction of research and development expenses.

The Company evaluates all Accounting Standards Updates (ASUs) issued by the FASB for consideration of their applicability to our consolidated financial statements. We have assessed all ASUs issued but not yet adopted and concluded that those not disclosed are not relevant to the Company or are not expected to have a material impact.

2. FAIR VALUE

In accordance with the Fair Value Measurements and Disclosures Topic of the FASB ASC 820, the Company groups its financial assets and financial liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value:

- Level 1: Input prices quoted in an active market for identical financial assets or liabilities.
- Level 2: Inputs other than prices quoted in Level 1, such as prices quoted for similar financial assets and liabilities in active markets, prices for identical assets, and liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Input prices quoted that are significant to the fair value of the financial assets or liabilities which are not observable or supported by an active market.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The carrying value of cash and cash equivalents approximates fair value as maturities are less than three months. The carrying amounts reported in the Condensed Consolidated Balance sheets for other current financial assets and liabilities approximate fair value because of their short-term nature.

In September 2023 the Company issued warrants to purchase shares of preferred stock which, on an as-converted basis, represent an aggregate of 21,025,641 shares of common stock (the September 2023 Warrants) (see Note 3). The fair value of the September 2023 Warrants was determined using a probability-weighted expected return method (PWERM) with a scenario-based Monte Carlo simulation and Black-Scholes model. The PWERM is a scenario-based methodology that estimates the fair value of the Company's

[Table of Contents](#)

different classes of equity based upon an analysis of future values for the Company, assuming various outcomes. Under both models, assumptions and estimates are used to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information that impacts the assumptions is obtained. The quantitative elements associated with the inputs impacting the fair value measurement of the September 2023 Warrants include the value per share of the underlying common stock, the timing, form and overall value of the expected exits for the stockholders, the risk-free interest rate, the expected dividend yield and the expected volatility of the Company's shares. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared cash dividends. Expected volatility was determined based upon the historical volatility of the Company's common stock. Due to the nature of these inputs and the valuation technique utilized, these warrants are classified within the Level 3 hierarchy. The Warrant Liability of \$8,600,000 presented on the accompanying Condensed Consolidated Balance Sheet as of September 30, 2023, consists entirely of the estimated value of the September 2023 Warrants.

The following table summarizes the modified option-pricing assumptions used on September 8, 2023, which was the date of issuance, and September 30, 2023:

	<u>September 8</u>	<u>September 30</u>
Volatility	83.0-84.0 %	83.0-84.0 %
Risk-free interest rate	4.39-5.53 %	4.61-5.55 %
Expected life (years)	0.4-5.0	0.3-5.0
Dividend	0 %	0 %

The following table summarizes the changes in the fair market value of the warrants which are classified within the Level 3 fair value hierarchy from September 8, 2023, which was the date of issuance, through September 30, 2023:

	<u>Level 3</u>
Beginning fair value of warrants	\$ 4,700,000
Loss from change in fair value	3,900,000
September 30, 2023 fair value of warrants	<u>\$ 8,600,000</u>

3. STOCKHOLDERS' EQUITY

September 2023 Private Placement

On September 8, 2023, in a private placement with certain institutional investors, the Company issued 1,225 shares of Series E-1 preferred stock, along with Tranche A warrants to purchase 2,205 shares of Series E-3 preferred stock and Tranche B warrants to purchase 1,715 shares of Series E-4 preferred stock. Shares of Series E preferred stock were issued at a fixed price of \$20,000 per share, resulting in gross proceeds of \$24.5 million and net proceeds of approximately \$22.1 million after placement agent fees and other customary expenses.

The private placement is subject to approval by the Company's stockholders. Upon approval (Note 9), the Series E-1 preferred stock will convert into either Series E-2 preferred stock and/or common stock. The conversion prices for the preferred stock are as follows: for the Series E-1 or E-2 preferred stock, \$1.82 per share of common stock, or a total of 13,461,538 shares of common stock; for the Series E-3 preferred stock, \$3.185 per share of common stock, or a total of 13,846,154 shares of common stock; and for the Series E-4 preferred stock, \$4.7775 per share of common stock, or a total of 7,179,487 shares of common stock, in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. The two tranches of warrants are exercisable as follows:

- Tranche A warrants, for an aggregate exercise price of approximately \$44.1 million, that are exercisable for Series E-3 preferred stock until the earlier of September 6, 2026, or 10 days following the Company's announcement of positive top-line data from the WM CLOVER-WaM pivotal trial; and,
- Tranche B warrants, for an aggregate exercise price of approximately \$34.3 million, that are exercisable for Series E-4 preferred stock until the earlier of September 6, 2028, or 10 days following the Company's public announcement of its receipt of written approval from the FDA of its New Drug Application for iopofosine I 131.

[Table of Contents](#)

The Series E-1 preferred stock has a redemption feature; therefore, it has been classified as mezzanine equity in the accompanying Condensed Consolidated Balance Sheets as of September 30, 2023. This feature only applies to the Series E-1 preferred stock; upon stockholder approval of the transaction the redemption feature will no longer exist (Note 9). The Series E-1 preferred stock is considered a freestanding instrument, as are the Tranche A and Tranche B warrants, however the warrants are not freestanding from each other and are considered one unit for accounting purposes.

The Series E-1 preferred stock also has a liquidation preference, which is calculated as an amount per share equal to the greater of (i) two times (2X) the Original Per Share Price, together with any declared, unpaid dividends, or (ii) such amount per share as would have been payable had all shares of Series E-1 preferred stock been converted into Common Stock immediately prior to such Liquidation. While the Series E-1 preferred stock is outstanding, both the Tranche A and Tranche B warrants are considered puttable by virtue of the liquidation preference impacting the disposition of these warrants in the event of a liquidation. In accordance with the guidance in Accounting Standards Codification section 480, a puttable warrant is deemed to be a liability. All such liabilities are required to be presented at fair value, with changes being reflected in financial results for the period. As a result, the net proceeds, as reduced by the direct costs of the financing, are allocated first to the warrant liability at fair value, with the residual amount presented in mezzanine equity in the accompanying Condensed Consolidated Balance Sheets, and the change in the value of the warrants from the date of issuance to the end of the fiscal period is reflected in the accompanying Condensed Consolidated Statements of Operations.

October 2022 Public Offering and Private Placement

On October 25, 2022, the Company completed a registered direct offering of 3,275,153 shares of the Company's common stock at \$2.085 per share and common warrants to purchase up to an aggregate of 3,275,153 shares of common stock in a concurrent private placement priced at-the-market under Nasdaq rules. In a separate concurrent private placement transaction, the Company offered and sold pre-funded warrants to purchase an aggregate of 1,875,945 shares of common stock and common warrants to purchase an aggregate of 1,875,945 shares of common stock. The common warrants are immediately exercisable at an exercise price of \$1.96 per share and will expire on the fifth anniversary of the closing date. Each pre-funded warrant has a purchase price of \$2.08499, is immediately exercisable at an exercise price of \$0.00001 per share and will not expire until exercised. The registered direct offering and private placements resulted in total gross proceeds of approximately \$10.7 million with net proceeds to the Company of approximately \$9.6 million after deducting estimated offering expenses. During the nine months ended September 30, 2023, 355,235 pre-funded warrants were converted into 355,235 shares of common stock. There were no pre-funded warrants exercised during the three months ended September 30, 2023. During the three months and nine months ended September 30, 2023, 177,877 common warrants were exercised for proceeds of \$348,638.

In accordance with the concept of ASC 820 regarding the October 2022 public offering, the Company allocated the value of the proceeds to the common stock, common warrants, and pre-funded warrants utilizing a relative fair value basis. Using the Nasdaq closing trading price for our stock on October 20, 2022, the Company computed the fair value of the shares sold. This valuation did not impact the total gross increase to Stockholders' Equity of \$10.7 million, but is an internal, proportionate calculation allocating gross proceeds of approximately \$4.0 million to common stock, \$4.4 million to common warrants and \$2.3 million to pre-funded warrants.

2022 Reverse Stock Split

At the annual stockholders' meeting held on June 24, 2022, the Company's stockholders approved an amendment to the Company's certificate of incorporation to effect a reverse split of the Company's common stock at a ratio between 1-for-5 to 1-for-10 in order to satisfy requirements for the continued listing of the Company's common stock on Nasdaq. The board of directors authorized the 1-for-10 ratio of the reverse split on June 27, 2022, and effective at the close of business on July 21, 2022, the Company's certificate of incorporation was amended to effect a 1-for-10 reverse split of the Company's common stock (the "Reverse Stock Split"). The accompanying consolidated financial statements and notes to consolidated financial statements give retroactive effect to the Reverse Stock Split for all periods presented.

Equity Distribution Agreement

On August 11, 2020, the Company entered into an equity distribution agreement (the Sales Agreement) with Oppenheimer & Co. Inc. (the Sales Agent). Pursuant to the Sales Agreement, the Company may offer and sell from time-to-time through the Sales Agent, up to \$14.5 million shares of the Company's common stock, par value \$0.00001 per share (the ATM Shares). The Sales Agent will receive from the Company a commission of 3.0% of the gross proceeds from the sales of the ATM Shares pursuant to the terms of the Sales Agreement. The offering of the ATM Shares pursuant to the Sales Agreement will terminate upon the earliest of (i) the sale of all

[Table of Contents](#)

ATM Shares subject to the Sales Agreement, and (ii) the termination of the Sales Agreement by the Company or the Sales Agent. Net proceeds from the sale of the ATM Shares will be used for general corporate purposes, including working capital.

In conjunction with the October 2022 offering, the Company filed a prospectus supplement suspending the ATM program. The Company will not make any sales of its common stock pursuant to the Equity Distribution Agreement unless and until a new registration statement of Form S-3 and a new prospectus supplement are filed with the SEC; however, the Equity Distribution Agreement remains in effect.

Common Stock Warrants

The following table summarizes information with regard to outstanding warrants to purchase common stock as of September 30, 2023:

Offering	Number of Shares Issuable Upon Exercise of Outstanding Warrants	Exercise Price	Expiration Date
2023 Tranche A Preferred Warrants	13,846,154	\$ 3.185	September 8, 2026 ⁽¹⁾
2023 Tranche B Preferred Warrants	7,179,487	\$ 4.7775	September 8, 2028 ⁽¹⁾
2022 Common Warrants	4,973,221	\$ 1.96	October 25, 2027
2022 Pre-Funded Warrants	1,520,710	\$ 0.00001	N/A
June 2020 Series H Warrants	720,796	\$ 12.075	June 5, 2025
May 2019 Series F Warrants	195,700	\$ 24.00	May 20, 2024
May 2019 Series G Warrants	201,800	\$ 24.00	May 20, 2024
October 2017 Series D Warrants	31,085	\$ 178.00	October 14, 2024
Total	28,668,953		

(1) These warrants are described further under the caption “September 2023 Private Placement” above.

4. STOCK-BASED COMPENSATION

Accounting for Stock-Based Compensation

Stock Incentive Plans

The Company maintains the 2021 Stock Incentive Plan (the “2021 Plan”). All outstanding awards under the 2015 Stock Incentive Plan (the “2015 Plan”) remained in effect according to the terms of the 2015 Plan. Any shares that are currently available under the 2015 Plan and any shares underlying 2015 Plan awards which are forfeited, cancelled, reacquired by the Company or otherwise terminated are added to the number of shares available for grant under the 2021 Plan.

The fair value of each stock award is estimated on the grant date using the Black-Scholes option-pricing model. Volatility is based on the Company’s historical common stock volatility. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time. The expected term of stock options granted is based on an estimate of when options will be exercised in the future. Forfeitures are recorded as they occur. No dividends have been recorded historically.

As of September 30, 2023, there were an aggregate of 351,254 shares available for future grants under the 2021 Plan.

During the nine months ended September 30, 2023 and 2022, options granted were 1,542,000 and 340,250, respectively.

[Table of Contents](#)

The following table summarizes the expense for stock-based compensation related to stock option grants:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Employee and director stock option grants:				
Research and development	\$ 89,172	\$ 37,211	\$ 227,896	\$ 123,638
General and administrative	408,706	330,548	1,097,945	967,879
Total stock-based compensation	<u>\$ 497,878</u>	<u>\$ 367,759</u>	<u>\$ 1,325,841</u>	<u>\$ 1,091,517</u>

On January 17, 2023, the Company granted 609,000 non-statutory stock option awards at an exercise price of \$1.68 per share to employees. These grants were contingent upon the approval of the increase in the number of shares available for issuance under the 2021 Plan that was approved by the stockholders at the Annual Meeting of Stockholders held on June 23, 2023. In accordance with the removal of the contingency, the Company began recognizing the expense for these awards beginning in June 2023.

5. INCOME TAXES

The Company accounts for income taxes in accordance with the liability method of accounting. Deferred tax assets or liabilities are computed based on the difference between the financial statement and income tax basis of assets and liabilities, and net operating loss carryforwards (“NOLs”), using the enacted tax rates. Deferred income tax expense or benefit is based on changes in the asset or liability from period to period. The Company did not record a provision or benefit for federal, state or foreign income taxes for the three months or nine months ended September 30, 2023 or 2022 because the Company has experienced losses on a tax basis since inception. Because of the limited operating history, continuing losses and uncertainty associated with the utilization of the NOLs in the future, management has provided a full allowance against the value of its gross deferred tax assets.

The Company also accounts for the uncertainty in income taxes related to the recognition and measurement of a tax position taken or expected to be taken in an income tax return. The Company follows the applicable accounting guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition related to the uncertainty in income tax positions. No uncertain tax positions have been identified.

6. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock and pre-funded warrants outstanding during the period. The pre-funded warrants are considered common shares outstanding for the purposes of the basic net loss per share calculation due to the nominal cash consideration and lack of other contingencies for issuance of the underlying common shares. Diluted net loss attributable to common stockholders per share is computed by dividing net loss attributable to common stockholders, as adjusted, by the sum of the weighted average number of shares of common stock and the dilutive potential common stock equivalents then outstanding. Potential common stock equivalents consist of stock options, warrants, and convertible preferred shares. Since there is a net loss attributable to common stockholders for the nine months ended September 30, 2023 and September 30, 2022, the inclusion of common stock equivalents in the computation for those periods would be antidilutive. Accordingly, basic and diluted net loss per share is the same for all periods presented.

The following potentially dilutive securities have been excluded from the computation of diluted net loss per share since their inclusion would be antidilutive:

	Nine Months Ended	
	September 30,	
	2023	2022
Warrants	27,148,243 ⁽¹⁾	1,563,381
Preferred shares as convertible into common stock	111,111	111,111
Stock options	2,280,756	654,263
Total potentially dilutive shares	<u>29,540,110</u>	<u>2,328,755</u>

[Table of Contents](#)

- (1) As of September 30, 2023 the Convertible Preferred Series E-1 Shares were not convertible, pending stockholder approval of the transaction and are therefore excluded from this table.

7. COMMITMENTS AND CONTINGENCIES

Legal

The Company may be involved in legal matters and disputes in the ordinary course of business. We do not anticipate that the outcome of such matters and disputes will materially affect the Company's financial statements.

8. LEASES

Operating Lease Liability

In June 2018, the Company executed an agreement for office space in the Borough of Florham Park, Morris County, New Jersey to be used as its headquarters (HQ Lease). The HQ Lease commenced upon completion of certain improvements in October 2018.

On December 30, 2022, the Company entered into an Amended Agreement of Lease of the HQ Lease (Amended HQ Lease), with CAMPUS 100 LLC (the "Landlord"). Under the Amended HQ Lease, which was accounted for as a modification of the initial lease, the Company will continue to lease 3,983 square feet of rentable area on the second floor of a building located at 100 Campus Drive in Florham Park, New Jersey, commencing on March 1, 2023 until April 30, 2029. The Company also has an option to extend the term of the Amended HQ Lease for one additional 60-month period.

Under the terms of the Amended HQ Lease, the Company paid a security deposit of \$23,566, and the aggregate rent due over the term of the Amended Lease is approximately \$918,000, which will be reduced to approximately \$893,000 after certain rent abatements. The Company will also be required to pay its proportionate share of certain operating expenses and real estate taxes applicable to the leased premises. After rent abatements, the rent is approximately \$11,800 per month for the first year and then escalates thereafter by 2% per year for the duration of the term. The Company has not entered into any leases with related parties.

Discount Rate

The Company has determined an appropriate interest rate to be used in evaluating the present value of the Amended Lease liability considering factors such as the Company's credit rating, borrowing terms offered by the U.S. Small Business Administration, amount of lease payments, quality of collateral and alignment of the borrowing term and lease term. The Company considers 14% per annum as reasonable to use as the incremental borrowing rate for the purpose of calculating the liability under the Amended Lease. In conjunction with the June 2018 lease, the Company had previously used a 10% per annum incremental borrowing rate.

Maturity Analysis of Short-Term and Operating Leases

The following table approximates the dollar maturity of the Company's undiscounted payments for its short-term leases and operating lease liabilities as of September 30, 2023:

Years ending September 30,	
2023	\$ 35,000
2024	132,000
2025	147,000
2026	150,000
2027	153,000
Thereafter	207,000
Total undiscounted lease payments	824,000
Less: Imputed interest	(255,000)
Present value of lease liabilities	<u>\$ 569,000</u>

9. SUBSEQUENT EVENT

September 2023 Private Placement Approval

The Company held a Special Meeting of Stockholders on October 25, 2023, for the purpose of presenting three proposals to the stockholders for approval. The first proposal was to request the stockholders approve the potential issuance in excess of 19.99% of currently outstanding common stock upon the conversion of the Series E preferred stock at less than the “minimum price” under Nasdaq Listing Rule 5635(d), and which may be deemed a “change of control” under Nasdaq Listing Rule 5635(b). The second proposal was to request the stockholders approve an increase in the Company’s authorized common stock from 160,000,000 to 170,000,000. The third proposal was to support the adjournment of the meeting in the event additional votes needed to be solicited. The stockholders approved all three proposals at the meeting.

Stockholder approval for the September 2023 Private Placement automatically causes the Series E-1 preferred stock to convert into either Series E-2 preferred stock or common stock. This eliminates the liquidation preference and redemption rights associated with the Series E-1 preferred stock.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

You should read the following discussion and analysis of our financial condition and results of operations together with the unaudited financial information and notes thereto included in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, include forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Annual Report on Form 10-K for the year ended December 31, 2022, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

We are a late-stage clinical biopharmaceutical company focused on the discovery, development and commercialization of drugs for the treatment of cancer. Our core objective is to leverage our proprietary phospholipid ether drug conjugate™ (PDC™) delivery platform to develop PDCs that are designed to specifically target cancer cells and deliver improved efficacy and better safety as a result of fewer off-target effects. We believe that our PDC platform possesses the potential for the discovery and development of the next generation of cancer-targeting treatments, and we plan to develop PDCs both independently and through research and development collaborations.

Uncertainties related to the continued impact of the COVID-19 pandemic on results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease or variants thereof, the duration of the pandemic, vaccination rates, travel restrictions and social distancing in the U.S., Canada and other countries, business closures or business disruptions, the ultimate impact on financial markets and the global economy, and the effectiveness of actions taken in the U.S., Canada and other countries to contain and treat the disease.

Our lead PDC therapeutic, iopofosine I 131, is a small-molecule PDC designed to provide targeted delivery of iodine-131 directly to cancer cells while limiting exposure to healthy cells. We believe this profile differentiates iopofosine I 131 from many traditional on-market treatments. Iopofosine I 131 is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with relapsed/refractory (r/r) WM, a Phase 2b study in r/r multiple myeloma (MM) patients and r/r central nervous system lymphoma (CNSL) and the CLOVER-2 Phase 1a study for a variety of pediatric cancers has concluded and a Phase 1b study in pediatric patients with high grade glioma is initiating. As with all clinical trials, adverse events, serious adverse events or fatalities may arise during a clinical trial due to medical problems that may not be related to clinical trial treatments.

The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies. The CLOVER-WaM Study is a pivotal registration study currently evaluating iopofosine in WM patients that were r/r to two prior lines of therapy including Bruton tyrosine kinase inhibitor (BTKi) failed or suboptimal response WM patients. The CLOVER-1 Phase 2b study, where iopofosine remains under further evaluation in highly refractory MM and CNSL patients, is ongoing.

The CLOVER-2 Phase 1a pediatric study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors (high grade glioma, and glioblastoma, etc.) for which there are no standard treatments. The study was conducted internationally at seven leading pediatric cancer centers. The CLOVER-2 Phase 1b pediatric study will be an open-label, dose finding study evaluating the activity of iopofosine in children and adolescents with r/r malignant brain tumors (high grade gliomas).

The U.S. Food and Drug Administration (FDA) granted iopofosine Fast Track Designation for lymphoplasmacytic lymphoma (LPL) and WM patients having received two or more prior treatment regimens, as well as r/r MM and r/r diffuse large B-cell lymphoma (DLBCL). Orphan Drug Designations (ODDs) have been granted for LPL/WM, MM, neuroblastoma, soft tissue sarcomas including rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. Iopofosine was also granted Rare Pediatric Disease Designation (RPDD) for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. The European Commission granted ODD for r/r MM and WM.

[Table of Contents](#)

Additionally, in June 2020, the European Medicines Agency (EMA) granted us Small and Medium-Sized Enterprise (SME) status by the EMA's Micro, Small and Medium-sized Enterprise office. SME status allows us to participate in significant financial incentives that include a 90% to 100% EMA fee reduction for scientific advice, clinical study protocol design, endpoints and statistical considerations, quality inspections of facilities and fee waivers for selective EMA pre-and post-authorization regulatory filings, including orphan drug and PRIME designations. We are also eligible to obtain EMA certification of quality and manufacturing data prior to review of clinical data. Other financial incentives include EMA-provided translational services of all regulatory documents required for market authorization, further reducing the financial burden of the market authorization process.

Our product pipeline also includes one preclinical PDC chemotherapeutic program (CLR 1900), a PDC-based alpha-emitter radiotherapeutic series (CLR12120) and several partnered PDC assets. The CLR 1900 Series is being developed for solid tumors with a payload that inhibit mitosis (cell division), a validated pathway for treating cancers. We are evaluating the CLR 12120 series with both actinium and astatine as future targeted alpha therapies.

We have leveraged our PDC platform to establish three ongoing collaborations featuring four unique payloads and mechanisms of action. Through research and development collaborations, our strategy is to generate near-term capital, supplement internal resources, gain access to novel molecules or payloads, accelerate product candidate development, and broaden our proprietary and partnered product pipelines.

Our PDC platform is designed to provide selective delivery of a diverse range of oncologic payloads to cancerous cells, whether a hematologic cancer or solid tumor, a primary tumor, or a metastatic tumor and cancer stem cells. The PDC platform's mechanism of entry is designed not to rely upon a specific cell surface epitope or antigen as are required by other targeted delivery platforms. Our PDC platform takes advantage of a metabolic pathway utilized by nearly all tumor cell types in all stages of the tumor cycle. Tumor cells modify the cell surface to create specific, highly organized microdomains as a result of the utilization of this metabolic pathway. Our PDCs are designed to bind to these regions and directly enter the intracellular compartment. This mechanism allows the PDC molecules to accumulate in tumor cells over time, which we believe can enhance drug efficacy. The direct intracellular delivery allows our molecules to avoid the specialized highly acidic cellular compartment known as lysosomes, which allows a PDC to deliver payloads that previously could not be delivered in this targeted manner. Additionally, molecules targeting specific cell surface epitopes face challenges in completely eliminating a tumor because the targeted antigens are limited in the total number on the cell surface, have longer cycling time from internalization to being present on the cell surface again diminishing their availability for binding and are not present on all of the tumor cells because of the heterogenous nature of cancer cells. This means a subpopulation of tumor cells always exist that cannot be targeted by therapies targeting specific surface epitopes. In addition to the benefits provided by the mechanism of entry, PDCs offer the ability to conjugate payload molecules in numerous ways, thereby increasing the types of molecules selectively delivered via the PDC.

The PDC platform features include the capacity to link with almost any molecule, provide a significant increase in targeted oncologic payload delivery and the ability to target all types of tumor cells. As a result, we believe that we can generate PDCs to treat a broad range of cancers with the potential to improve the therapeutic index of oncologic drug payloads, enhance or maintain efficacy while also reducing adverse events by minimizing drug delivery to healthy cells, and increasing delivery to cancerous cells and cancer stem cells.

We employ a drug discovery and development approach that allows us to efficiently design, research and advance drug candidates. Our iterative process allows us to rapidly and systematically produce multiple generations of incrementally improved targeted drug candidates.

A description of our PDC product candidates follows:

Clinical Pipeline

Our lead PDC therapeutic, iopofosine I 131, is currently being evaluated in the CLOVER-WaM Phase 2 pivotal study in patients with r/r WM, a Phase 2b study in r/r MM patients and the CLOVER-2 Phase 1 study for a variety of pediatric cancers. Adverse events across all studies have been largely restricted to fatigue (39)% and cytopenias, specifically, thrombocytopenia (75)%, anemia (61)%, neutropenia (54)%, leukopenia (56)%, and lymphopenia (34)%. Patients in our clinical trials have developed infections (<4%) and in at least one instance led to a fatality possibly attributed to iopofosine.

[Table of Contents](#)

The CLOVER-WaM pivotal Phase 2b study is enrolling WM patients that have received at least two previous lines of therapy including those that failed or had a suboptimal response to a BTKi therapy. The CLOVER-1 Phase 2 study met the primary efficacy endpoints from the Part A dose-finding portion, conducted in r/r B-cell malignancies, and is now enrolling an MM and CNSL expansion cohort (Phase 2b). The Phase 2b study will evaluate highly refractory MM patients who are triple, quad and penta class refractory, including post-BCMA immunotherapy patients and r/r CNSL patients. The initial Investigational New Drug (IND) application was accepted by the FDA in March 2014 with multiple INDs submitted since that time. The Phase 1 study was designed to assess the compound's safety and tolerability in patients with r/r MM, and to determine maximum tolerated dose (MTD), and was initiated in April 2015. The study completed enrollment and the final clinical study report was filed in second half 2022. Initiated in March 2017, the primary goal of the Phase 2a study was to assess the compound's efficacy in a broad range of hematologic cancers. In February 2023, we announced that a CNSL patient treated as part of the Phase 2b study achieved a complete response, or full resolution of their tumor, as verified by imaging. We have expanded the CNSL cohort to further evaluate iopofosine I 131 in this indication.

The CLOVER-2 Phase 1a pediatric study was conducted internationally at seven leading pediatric cancer centers. The study was an open-label, sequential-group, dose-escalation study to evaluate the safety and tolerability of iopofosine in children and adolescents with relapsed or refractory cancers, including malignant brain tumors, neuroblastoma, sarcomas, and lymphomas (including Hodgkin's lymphoma). The maximum tolerated dose was determined to be greater than 60mCi/m² administered as a fractionated dose. CLOVER-2 Phase 1b study is an open-label, international dose finding study evaluating iopofosine in r/r pediatric patients with high grade gliomas. These cancer types were selected for clinical, regulatory and commercial rationales, including the radiosensitive nature and continued unmet medical need in the r/r setting, and the rare disease determinations made by the FDA based upon the current definition within the Orphan Drug Act.

In December 2014, the FDA granted ODD for iopofosine for the treatment of MM. In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. In May 2019, the FDA granted Fast Track designation for iopofosine for the treatment of MM and in July 2019 for the treatment of DLBCL. In September 2019 iopofosine received ODD from the European Union for MM. In December 2019, the FDA and the European Union each granted ODD for iopofosine for the treatment of WM. The FDA granted Fast Track designation for iopofosine for the treatment of r/r LPL and WM in May 2020.

As the result of iopofosine's RPDD designation, we may be eligible to receive a priority review voucher (PRV) if the product receives approval for any of the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma or osteosarcoma. The FDA may award PRV to sponsors of a product application for a RPDD that meet its specified criteria. The key criteria to receiving PRV is that the drug be approved for a rare pediatric disease and treat a serious or life-threatening manifestation of the disease or condition that primarily affects individuals under the age of 18. In order to receive a PRV, a sponsor must obtain approval of a "rare pediatric disease product application," which is a human drug application for prevention or treatment of a rare pediatric disease and which contains no active ingredient, including any ester or salt thereof, that has been approved by the FDA; is deemed eligible for priority review; is submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 351(a) of the Public Health Service Act (PHSA); relies on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population; does not seek approval for an adult indication in the original rare pediatric disease application; and is approved after September 30, 2016. Under this program, a sponsor who receives an approval for a drug or biologic for a rare pediatric disease can receive a PRV that can be redeemed to receive a priority review of a subsequent marketing application for a different product. Additionally, the PRV's can be exchanged or sold to other companies so that the receiving company may use the voucher. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives RPDD before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

CLOVER-WaM: Phase 2 Pivotal Study in: Patients with r/r Waldenstrom's Macroglobulinemia

In January 2021, we announced that we participated in a Type C guidance meeting with the FDA in September 2020. The results of that guidance meeting provided Cellectar with an agreed upon path for conducting the CLOVER-WaM study; a single arm, pivotal study in WM patients that have received and relapsed or were refractory to two prior lines of therapy including failed or had a suboptimal response to BTKi therapy. WM is a rare, indolent and incurable form of non-Hodgkin's lymphoma (NHL) that is composed of a patient population in need of new and better treatment options.

The study is expected to enroll at least 50 WM patients who have received at least two prior lines of therapy, failed both lines of therapy including having failed or had a suboptimal response to a BTKi (i.e. ibrutinib). Patients in the trial will receive up to 4-doses of iopofosine over two cycles (cycle one days 1, 15, and cycle two days 57, 71) with each dose administered as a 15mCi/m² infusion. The primary endpoint of the trial is major response rate (MRR) as defined as a partial response (a minimum of a 50% reduction in IgM) or better in patients that receive a minimum total body dose (TBD) of 60 mCi with secondary endpoints of treatment free survival (treatment free remission), duration of response and progression free survival. An independent data monitoring committee (IDMC) performed an interim safety and futility evaluation on the first 10 patients enrolled. If three of the 10 patients experienced a Clinically Significant Toxicity (CST) then the dose would have been reduced to 12.5 mCi/m². We believe this design is aligned with the feedback received from the FDA during the guidance meeting held in September 2020. The FDA accepted the dose to be tested, our proposal for a safety and futility assessment to be conducted on the first 10 patients, the endpoint to be assessed, the statistical analysis plan and study size of 50 patients. Based on this agreement the pivotal study was initiated. The interim futility and safety assessment occurred in 2022 and iDMC determined the study exceeded the futility threshold and that the CST threshold was not met therefore the study should continue to enroll with no change to the dosing regimen. We have completed site enrollment, and expect to release top-line data from the study in January 2024.

CLOVER-1: Phase 2 Study in Select B-Cell Malignancies

The Phase 2 CLOVER-1 study was an open-label study designed to determine the efficacy and safety of CLR 131 in select B-cell malignancies (multiple myeloma (MM), indolent chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), lymphoplasmacytic lymphoma (LPL)/Waldenstrom's macroglobulinemia (WM), marginal zone lymphoma (MZL), mantle cell lymphoma (MCL), DLBCL, and central nervous system lymphoma (CNSL) who have been previously treated with standard therapy for their underlying malignancy. As of March 2022, the study arms for CLL/SLL, LPL/WM, MZL, MCL, and DLBCL were closed. Dosing of patients varied by disease state cohort and was measured in terms of TBD.

In July 2016, we were awarded a \$2,000,000 National Cancer Institute (NCI) Fast-Track Small Business Innovation Research grant to further advance the clinical development of iopofosine. The funds supported the Phase 2 study initiated in March 2017 to define the clinical benefits of iopofosine in r/r MM and other niche hematologic malignancies with unmet clinical need. These niche hematologic malignancies include CLL, SLL, MZL, LPL/WM and DLBCL. The study was conducted in approximately 10 U.S. cancer centers in patients with orphan-designated relapse or refractory hematologic cancers. The planned study enrollment was up to 80 patients.

The study's primary endpoint was clinical benefit response (CBR), with secondary endpoints of overall response rate (ORR), progression free survival (PFS), time to next treatment (TtNT), median Overall Survival (mOS), duration of response (DOR) and other markers of efficacy following patients receiving one of three TBDs of iopofosine (<50mCi, ~50mCi and >60mCi), with the option for a second cycle approximately 75-180 days later. Dosages were provided either as a single bolus or fractionated (the assigned dose level split into two doses) given day 1 and day 15. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m² per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Adverse events occurring in at least 25% of subjects were fatigue (39)% and cytopenias, specifically, thrombocytopenia (75)%, anemia (61)%, neutropenia (54)%, leukopenia (51)%, and lymphopenia (25)%. Serious adverse events occurring in greater than 5% of subjects were restricted to thrombocytopenia (9)% and febrile neutropenia (7.5)%.

Phase 2a Study: Patients with r/r Waldenstrom's Macroglobulinemia Cohort

Patients in the r/r WM cohort all received TBD of ≥ 60 mCi (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles of mCi/m² fractionated) either as a bolus dose or fractionated. Current data from our Phase 2a CLOVER-1 clinical study show a 100% ORR in 6 WM patients and an 83.3% major response rate with one patient achieving a complete response (CR), which continues at nearly 27 months post-last treatment. While median treatment free survival (TFS), also known as treatment free remission (TFR), and DOR have not been reached, the average treatment TFS/TFR is currently at 330 days. This may represent an important improvement in the treatment of r/r WM as we believe no approved or late-stage development treatments for second- and third-line patients have reported a CR to date. Based on study results to date, patients continue to tolerate iopofosine well, with the most common adverse events being cytopenias and fatigue.

Phase 2a Study: Patients with r/r Multiple Myeloma Cohort

In September 2020, we announced that a 40% ORR was observed in the subset of refractory multiple myeloma patients deemed triple class refractory who received 60 mCi or greater TBD. Triple class refractory is defined as patients that are refractory to immunomodulatory, proteasome inhibitors and anti-CD38 antibody drug classes. The 40% ORR (6/15 patients) represents triple class refractory patients enrolled in Part A of Cellectar's CLOVER-1 study and additional patients enrolled in Part B from March through May 2020 and received ≥ 60 mCi TBD (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles of mCi/m² fractionated) either as a bolus dose or fractionated. Patients with MM received 40 mg of dexamethasone concurrently beginning within 24 hours of the first CLR 131 infusion. All MM patients enrolled in the expansion cohort are required to be triple class refractory. The additional six patients enrolled in 2020 were heavily pre-treated with an average of nine prior multi-drug regimens. Three patients received a TBD of ≥ 60 mCi and three received less than 60 mCi. Consistent with the data released in February 2020, patients receiving ≥ 60 mCi typically exhibit greater responses. Based on study results to date, patients continue to tolerate iopofosine well, with the most common and almost exclusive treatment-emergent adverse events are cytopenias, such as thrombocytopenia, neutropenia, and anemia.

In December 2021, we presented data from 11 MM patients from our ongoing Phase 2 CLOVER-1 study in a poster at the American Society of Hematology (ASH) Annual Meeting and Exposition. The MM patients were at least triple class refractory (defined as refractory to an immunomodulatory agent, proteasome inhibitor and monoclonal antibody) with data current as of the end of May 2021. Patients had a median of greater than 7 prior therapies with 50% classified as high risk. Initial results in these patients showed an ORR of 45.5%, a CBR of 72.7% and a disease control rate (DCR) of 100%. Median PFS was 3.4 months. In a subset of 5 quad/penta drug refractory patients, efficacy increased, demonstrating an ORR of 80% and CBR of 100% in this highly treatment refractory group. The most commonly observed treatment emergent adverse events were cytopenias that included Grade 3 or 4 thrombocytopenia (62.5%), anemia (62.5%), neutropenia (62.5%) and decreased white blood cell count (50%). Treatment emergent adverse events were mostly limited to bone marrow suppression in line with prior observations. No patients experienced a treatment emergent adverse event of neuropathy, arrhythmia, cardiovascular event, bleeding, ocular toxicities, renal function, alterations in liver enzymes, or infusion-site reactions or adverse events. We continue to enrich the r/r MM patient cohort with patients that are even more refractory. Specifically enrolling patients that are quad-class refractory (triple class plus refractory to any of the recent approved product classes) and have relapsed post-BCMA immunotherapy. We reported in the Blood Cancer Journal in August 2022, that iopofosine demonstrated a 50% ORR in patients receiving ≥ 60 mCi total administered dose (3/6 patients). In June 2023, we presented data at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting from 64 evaluable, relapsed, or refractory multiple myeloma (MM) patients. Of these patients, 28 received the optimal dose of >60 mCi and demonstrated an overall response rate (ORR) of 32%, a clinical benefit rate (CBR) of 75% and a disease control rate (DCR) of 85.7%.

Phase 2a: Patients with r/r non-Hodgkin's lymphoma Cohort

In February 2020, we announced positive data from our Phase 2a CLOVER-1 study in patients with NHL patients were treated with three different doses (<50 mCi, ~ 50 mCi and ≥ 60 mCi TBD. Patients in the r/r NHL cohort received TBD of either ≥ 60 mCi or < 60 mCi (25 mCi/m² single bolus, 31.25 mCi/m² fractionated, 37.5 mCi/m² fractionated, or two cycles of mCi/m² fractionated) either as a bolus dose or fractionated. Patients with r/r NHL who received <60 mCi TBD and the ≥ 60 mCi TBD had a 42% and 43% ORR, respectively and a combined rate of 42%. These patients were also heavily pre-treated, having a median of three prior lines of treatment (range, 1 to 9) with the majority of patients being refractory to rituximab and/or ibrutinib. The patients had a median age of 70 with a range of 51 to 86. All patients had bone marrow involvement with an average of 23%. In addition to these findings, subtype assessments were completed in the r/r B-cell NHL patients. Patients with DLBCL demonstrated a 30% ORR with one patient achieving a CR, which continues at nearly 24 months post-treatment. The ORR for CLL/SLL and MZL patients was 33%.

Based upon the dose response observed in the Phase 2a study for patients receiving TBDs of 60mCi or greater, we determined that patient dosing of iopofosine in the pivotal study would be ≥ 60 mCi TBD. Therefore, patients are now grouped as receiving <60 mCi or ≥ 60 mCi TBD.

The most frequently reported adverse events in all patients were cytopenias, which followed a predictable course and timeline. The frequency of adverse events did not increase as doses were increased and the profile of cytopenias remains consistent. Importantly, our assessment is that these cytopenias have had a predictable pattern to initiation, nadir and recovery and are treatable. The most common grade ≥ 3 events at the highest dose (75mCi TBD) were hematologic toxicities including thrombocytopenia (65%), neutropenia (41%), leukopenia (30%), anemia (24%) and lymphopenia (35%). No patients experienced cardiotoxicities, neurological toxicities, infusion site reactions, peripheral neuropathy, allergic reactions, cytokine release syndrome, keratopathy, renal toxicities, or changes in liver enzymes. The safety and tolerability profile in patients with r/r NHL was similar to r/r MM patients except for fewer cytopenias of any grade. Based upon iopofosine being well tolerated across all dose groups, the observed response rate, and especially in difficult to treat patients such as high risk and triple class refractory or penta-refractory, and corroborating data showing the potential to further improve upon current ORRs and durability of those responses, the study has been expanded to test a two-cycle dosing optimization regimen with a target TBD ≥ 60 mCi/m² of iopofosine.

In May 2020, we announced that the FDA granted Fast Track Designation for iopofosine in WM in patients having received two or more prior treatment regimens.

Phase 1 Study in Patients with r/r Multiple Myeloma

In February 2020, final results from a multicenter, Phase 1 dose escalation clinical trial of iopofosine in r/r MM were presented. The trial was designed to evaluate the safety and potential initial efficacy of iopofosine administered in an up to 30-minute I.V. infusion either as a single bolus dose or as a fractionated dose in heavily pretreated MM patients. The study enrolled a total of 26 evaluable patients at three trial sites. For the trial, which used a modified 3 + 3 dose escalation design, 15 evaluable patients were dosed in single bolus doses from 12.5mCi/m² up to 31.25mCi/m² (TBD 20.35-59.17 mCi) and 11 evaluable patients were dosed in fractionated dosing cohorts of 31.25mCi/m² to 40mCi/m² (TBD 54.915-89.107 mCi). An iDMC did not identify dose-limiting toxicities in any cohort. Of the 26 evaluable patients in the trial, a partial response was observed in 4 of 26 patients (15.4%) and stable disease or minimal response in 22 of 26 patients (84.6%), for a disease control rate of 100%. A significant decrease in M-protein and FLC was also observed.

Iopofosine in combination with dexamethasone was under investigation in adult patients with r/r MM. Patients had to be refractory to or relapsed from at least one proteasome inhibitor and at least one immunomodulatory agent. The clinical study was a standard three-plus-three dose escalation safety study to determine the maximum tolerable dose. We use the International Myeloma Working Group (IMWG) definitions of response, which involve monitoring the surrogate markers of efficacy, M protein and FLC. The IMWG defines a PR as a greater than or equal to 50% decrease in FLC levels (for patients in whom M protein is unmeasurable) or 50% or greater decrease in M protein. Multiple myeloma is an incurable cancer of the plasma cells and is the second most common form of hematologic cancer. Secondary objectives included the evaluation of therapeutic activity by assessing surrogate efficacy markers, which include M protein, free light chain (FLC), PFS and OS. All patients were heavily pretreated with an average of five prior lines of therapy. An IDMC assessed the safety of iopofosine up to its planned maximum single, bolus dose of 31.25 mCi/m² or a TBD of ~63 mCi. The four single dose cohorts examined were: 12.5 mCi/m² (~25mCi TBD), 18.75 mCi/m² (~37.5mCi TBD), 25 mCi/m² (~50mCi TBD), and 31.25 mCi/m² (~62.5mCi TBD), all in combination with low dose dexamethasone (40 mg weekly). Of the five patients in the first cohort, four were assessed as achieving stable disease and one patient progressed at Day 15 after administration and was taken off the study. Of the five patients admitted to the second cohort, all five were assessed as achieving stable disease; however, one patient progressed at Day 41 after administration and was taken off the study. Four patients were enrolled to the third cohort, and all were assessed as achieving stable disease. In September 2017, we announced safety and tolerability data for cohort 4, in which patients were treated with a single infusion up to 30-minutes of 31.25mCi/m² of iopofosine, which was tolerated by the three patients in the cohort. Additionally, all three patients experienced CBR with one patient achieving a partial response (PR). The patient experiencing a PR had an 82% reduction in FLC. This patient did not produce M protein, had received seven prior lines of treatment including radiation, stem cell transplantation and multiple triple combination treatments including one with daratumumab that was not tolerated. One patient experiencing stable disease attained a 44% reduction in M protein. In January 2019, we announced that the pooled mOS data from the first four cohorts was 22.0 months. In late 2018, we modified this study to evaluate a fractionated dosing strategy to potentially increase efficacy and decrease adverse events.

Cohort 5 and cohort 6 received fractionated dosing of 31.25 mCi/m² (~62.5mCi TBD) and 37.5 mCi/m² (~75mCi TBD), each administered on day 1 and on day 8. Following the determination that all prior dosing cohorts were tolerated, we initiated a cohort 7 utilizing a 40mCi/m² (~95mCi TBD) fractionated dose administered 20mCi/m² (~40mCi TBD) on days 1 and day 8. Cohort 7 was the highest pre-planned dose cohort and subjects have completed the evaluation period. The study completed enrollment and the final clinical study report is expected in the first half of 2022. Adverse events occurring in at least 25% of subjects were fatigue (26%) and cytopenias, specifically, thrombocytopenia (90%), anemia (65%), neutropenia (55%), leukopenia (61%), and lymphopenia (58%). Serious adverse events occurring in greater than 2 subjects were restricted to febrile neutropenia n=3 (9.7%).

In May 2019, we announced that the FDA granted Fast Track Designation for iopofosine in fourth line or later r/r MM. Iopofosine is currently being evaluated in our ongoing CLOVER-1 Phase 2 clinical study in patients with r/r MM and other select B-cell lymphomas. Patients in the study received up to 4, approximately 20-minute IV infusions of iopofosine over 3 months, with doses given 14 days apart in each cycle and a maximum of 2 cycles. Low dose dexamethasone 40 mg weekly (20mg in patients \geq 75), was provided for up to 12 weeks. The planned study enrollment was up to 80 patients. Its primary endpoint was clinical benefit rate (CBR), with additional endpoints of ORR, PFS, median overall survival (OS) and other markers of efficacy. Over the course of the study the dosing regimen of iopofosine advanced from a single bolus dose to two cycles of fractionated administrations of 15 mCi/m² per dose on days 1, 15 (cycle 1), and days 57, 71 (cycle 2). Following treatment with iopofosine, approximately 91% of patients experience a reduction in tumor marker with approximately 73% experiencing greater than 37% reduction.

CLOVER 2: Phase 1 Study in r/r Pediatric Patients with select Solid tumors, Lymphomas and Malignant Brain Tumors

In December 2017, the Division of Oncology at the FDA accepted our IND and study design for the Phase 1 study of iopofosine in children and adolescents with select rare and orphan designated cancers. This study was initiated during the first quarter of 2019. In December 2017, we submitted an IND application for r/r pediatric patients with select solid tumors, lymphomas and malignant brain tumors. The Phase 1 clinical study of iopofosine is an open-label, sequential-group, dose-escalation study evaluating the safety and tolerability of intravenous administration of iopofosine in children and adolescents with relapsed or refractory malignant solid tumors (neuroblastoma, Ewing's sarcoma, osteosarcoma, rhabdomyosarcoma) and lymphoma or recurrent or refractory malignant brain tumors for which there are no standard treatments. Secondary objectives of the study are to identify the recommended efficacious dose of iopofosine and to determine preliminary antitumor activity (treatment response) of iopofosine in children and adolescents.

In August 2020, based on data on four dose levels from 15mCi/m² up to 60mCi/m², the iDMC permitted the beginning of the evaluation of the next higher dose cohort, at 75mCi/m². The iDMC advised, based upon the initial data, to enrich the 60 mCi/m² dose level for patients over the age of 10 with HGG and Ewing sarcoma. Changes in various tumor parameters appeared to demonstrate initial response and tumor uptake. This includes patients with relapsed HGGs with over 5 months of PFS. In November 2020, we announced clinical data providing that iopofosine had been measured in pediatric brain tumors, confirming that systemic administration of iopofosine crosses the blood brain barrier and is delivered into tumors and that the data show disease control in heavily pretreated patients with ependymomas. In November 2021, we announced favorable data on changes in various tumor parameters in a Phase 1 study in children and adolescents with relapsed and refractory high-grade gliomas (HGGs) and soft tissue sarcomas. Pediatric HGGs are a collection of aggressive brain and central nervous system tumor subtypes (i.e. diffuse intrinsic pontine gliomas, glioblastomas, astrocytomas, ependymomas, etc.) with about 400 new pediatric cases diagnosed annually in the U.S. Children with these tumors have a poor prognosis and limited 5-year survival. Adverse events occurring in at least 25% of subjects were fatigue, headache, nausea and vomiting (28% respectively), and cytopenias, specifically, thrombocytopenia (67%), anemia (67%), neutropenia (61%), leukopenia (56%), and lymphopenia (33%). There were no serious adverse events occurring in more than two subjects. The Part A portion of this Phase 1 study has concluded and part B is initiating to determine the appropriate dosing regimen in pediatric patients with r/r HGG. In 2022, the NCI award Collectar a \$1.9M SBIR Phase 2 grant to explore iopofosine in pediatric HGG. With this support, the company announced the initiation of a Phase 1b dose-finding study in pediatric high-grade gliomas (pHGGs) in the third quarter of 2023.

In 2018, the FDA granted ODD and RPDD for iopofosine for the treatment of neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma and osteosarcoma. If iopofosine should be approved for any of these pediatric indications, the first approved RPDD would enable us to receive a priority review voucher. Priority review vouchers can be used by the sponsor to receive priority review for a future New Drug Application (NDA) or Biologic License Application (BLA) submission, which would reduce the FDA review time from 12 months to six months. Currently, these vouchers can also be transferred or sold to another entity. In December 2020, the FDA extended the Priority Review Voucher Program through September 2026 for rare pediatric diseases.

Phase 1 Study in r/r Head and Neck Cancer

In August 2016, the University of Wisconsin Carbone Cancer Center (UWCCC) was awarded a five-year Specialized Programs of Research Excellence (SPORE) grant of \$12,000,000 from the NCI and the National Institute of Dental and Craniofacial Research to improve treatments and outcomes for head and neck cancer (HNC) patients. HNC is the sixth most common cancer across the world with approximately 56,000 new patients diagnosed every year in the U.S. As a key component of this grant, the UWCCC researchers completed testing of iopofosine in various animal HNC models and initiated the first human clinical study enrolling up to 30 patients combining iopofosine and external beam radiation treatment (EBRT) with recurrent HNC in the fourth quarter of 2019. UWCCC has completed the part A portion of a safety and tolerability study of iopofosine in combination with EBRT and preliminary data suggest safety and tolerability in relapsed or refractory HNC. The reduction in the amount or fractions (doses) of EBRT has the potential to diminish the (number and severity of) adverse events associated with EBRT. Patients with HNC typically receive approximately 60-70 Grays (Gy) of EBRT given as 2 – 3 Gy daily doses over a 6-week timeframe. Patients can experience long-term tumor control following re-irradiation in this setting; however, this approach can cause severe injury to normal tissue structures, significant adverse events and diminished quality of life. Part B of the study was to assess the safety and potential benefits of iopofosine in combination with EBRT in a cohort of up to 24 patients. This portion of the study has fully enrolled. Adverse events occurring in at least 25% of subjects were fatigue (46%) and cytopenias, specifically, thrombocytopenia (69%), anemia (77%), neutropenia (54%), leukopenia (69%), and lymphopenia (62%). There were no serious adverse events occurring in more than 2 subjects.

Preclinical Pipeline

We believe our PDC platform has potential to provide targeted delivery of a diverse range of oncologic payloads, as exemplified by the product candidates listed below, that may result in improvements upon current standard of care (SOC) for the treatment of a broad range of human cancers:

- CLR 1900 Series is an internally developed proprietary PDC program leveraging a novel small molecule cytotoxic compound as the payload. The payload inhibits mitosis (cell division) and targets a key pathway required to inhibit rapidly dividing cells that results in apoptosis. We believe that this program could produce a product candidate targeted to select solid tumors. Currently, the program is in early preclinical development and if we elect to progress any molecules further, we will select preferred candidates.
- CLR 12120 Series is an alpha emitting radio-conjugate program. A collaboration with Orano Med was initiated to validate the potential of this class of PDC radio-conjugates and for the potential development of novel PDCs utilizing Orano Med's unique alpha emitter, lead 212 conjugated to our phospholipid ether. The companies evaluated the new PDCs in three oncology indications. The collaboration successfully met its goals with the in vivo animal data demonstrating that the PDC combined with an alpha emitting radioisotope resulted in significant reduction in tumor volumes in all animal models tested. Celectar is now focused on utilizing this series in combination with actinium and astatine.
- The collaboration with IntoCell Inc., successfully met its agreed upon endpoint. The collaboration provided significant data which has led Celectar to select a series of highly potent cytotoxic small molecule payloads for further development.
- Co-development and commercialization collaboration with LegoChemBio, a clinical stage biotechnology company, to utilize their proprietary drug conjugate linker-toxin platform to further enhance our portfolio of next generation PDC therapeutics.

Results of Operations

Research and development expense. Research and development expense consist of costs incurred in identifying, developing and testing, and manufacturing product candidates, which primarily include salaries and related expenses for personnel, cost of manufacturing materials and contract manufacturing fees paid to contract manufacturers and contract research organizations, fees paid to medical institutions for clinical studies, and costs to secure intellectual property. The Company analyzes its research and development expenses based on four categories as follows: clinical project costs, preclinical project costs, manufacturing and related costs, and general research and development costs that are not allocated to the functional project costs, including personnel costs, facility costs, related overhead costs and patent costs.

General and administrative expense. General and administrative expense consists primarily of salaries and other related costs for personnel in executive, finance and administrative functions. Other costs include insurance, costs for public company activities, investor relations, directors' fees and professional fees for legal and accounting services.

Three Months Ended September 30, 2023 and 2022

Research and Development. Research and development expense for the three months ended September 30, 2023 was approximately \$7,313,000, compared to approximately \$5,380,000 for the three months ended September 30, 2022.

The following table is a summary comparison of approximate research and development costs for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Variance
	2023	2022	
Clinical project costs	\$ 3,412,000	\$ 3,720,000	\$ (308,000)
Manufacturing and related costs	2,832,000	1,049,000	1,783,000
Pre-clinical project costs	206,000	89,000	117,000
General research and development costs	863,000	522,000	341,000
	<u>\$ 7,313,000</u>	<u>\$ 5,380,000</u>	<u>\$ 1,933,000</u>

The overall increase in research and development expense of approximately \$1,933,000, or 36%, was primarily a result of increased manufacturing and related costs of approximately \$1,783,000 related to production sourcing and general research and development costs of approximately \$341,000 due to an increase in personnel offset by a reduction in clinical project cost of approximately \$308,000.

General and administrative. General and administrative expense for the three months ended September 30, 2023 was approximately \$2,101,000, compared to approximately \$2,435,000 for the same period in 2022. The overall decrease in general and administrative expense of \$334,000, or 14%, was primarily driven by a decrease in professional fees offset by a slight increase in personnel costs.

Nine Months Ended September 30, 2023 and 2022

Research and Development. Research and development expense for the nine months ended September 30, 2023 was approximately \$20,275,000, compared to approximately \$13,766,000 for the nine months ended September 30, 2022.

The following table is a summary comparison of approximate research and development costs for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Variance
	2023	2022	
Clinical project costs	\$ 10,235,000	\$ 9,715,000	\$ 520,000
Manufacturing and related costs	7,007,000	3,011,000	3,996,000
Pre-clinical project costs	422,000	191,000	231,000
General research and development costs	2,611,000	849,000	1,762,000
	<u>\$ 20,275,000</u>	<u>\$ 13,766,000</u>	<u>\$ 6,509,000</u>

The overall increase in research and development expense of approximately \$6,509,000, or 47%, was primarily a result of increased manufacturing and related costs of approximately \$3,996,000 related to production sourcing, increased clinical project costs of approximately \$508,000 driven by the timing of the activities related to our pivotal trial, and higher general research and development costs of approximately \$1,762,000 due to an increase in personnel and professional fees.

[Table of Contents](#)

General and administrative. General and administrative expense for the nine months ended September 30, 2023 was approximately \$6,138,000, compared to approximately \$7,625,000 for the same period in 2022. The overall decrease in general and administrative expense of \$1,487,000, or 20%, was primarily driven by a decrease in professional fees offset by a slight increase in personnel costs.

Liquidity and Capital Resources

We have incurred losses since inception in devoting substantially all of our efforts toward research and development. During the nine months ended September 30, 2023, we generated a net loss of approximately \$30.5 million, and used approximately \$23 million in cash for operations. We expect that we will continue to generate operating losses for the foreseeable future. As of September 30, 2023, our consolidated cash balance was approximately \$19 million. We believe our cash balance as of September 30, 2023 is adequate to fund our basic budgeted operations into the second quarter of 2024. Our ability to execute our operating plan beyond that time depends on our ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. We plan to actively pursue all available financing alternatives; however, there can be no assurance that we will obtain the necessary funding. Other than the uncertainties regarding our ability to obtain additional funding and our ability to meet the continued listing standards of Nasdaq, there are currently no known trends, demands, commitments, events or uncertainties that are likely to materially affect our liquidity.

Change in Significant Accounting Policies

The Company's significant accounting policies are disclosed in Note 2 to the Condensed Consolidated Financial Statements included in this Form 10-Q. There were no material changes to the significant accounting policies during the nine months ended September 30, 2023, except for the addition of the accounting policies for warrants and preferred stock. See Item 4 below.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 4. Controls and Procedures

Management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer (its principal executive officer and principal accounting officer, respectively) maintains "disclosure controls and procedures," as such terms are defined in Rules 13a 15(e) and 15d 15(e) of the Exchange Act, that are designed to ensure that information required to be disclosed by the Company in reports that we file or submit under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures. Based on management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2023, our management has concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms as a result of the material weakness identified below.

The material weakness described herein did not result in any identified misstatements to the financial statements, and there were no changes to our historical consolidated financial statements. Notwithstanding such material weakness, our consolidated financial statements and other financial information included in this Quarterly Report on Form 10-Q present fairly in all material respects our financial condition, results of operations, and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

During the period ended September 30, 2023, management identified a material weakness in our internal control over financial reporting due to the fact that we failed to design and implement adequate internal controls over financial reporting as it relates to the proper fair value methodologies and assumptions used to value Level 3 instruments. Our management, with oversight from our Audit Committee, is in the process of developing and implementing remediation plans in response to the identified material weakness described above.

[Table of Contents](#)

Changes in internal control over financial reporting. Based on management's evaluation (with the participation of our principal executive officer and principal financial officer), as of September 30, 2023, our management has concluded that there have not been any significant changes in the Company's internal control over financial reporting other than the material weakness and related remediation measures as described above.

The Chief Executive Officer and the Audit Committee perform significant roles in ensuring the accuracy and completeness of our financial reporting and the effectiveness of our disclosure controls and procedures. We have not identified any changes that occurred during the Company's fiscal quarter ended September 30, 2023 that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting other than the material weakness and related remediation measures as described above.

Important Considerations. Any system of controls, however well designed and operated, can provide only reasonable, and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part on certain assumptions about the likelihood of future events. The effectiveness of our disclosure controls and procedures is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Because of these and other inherent limitations of control systems, there can be no assurance that any system of disclosure controls and procedures will be successful in achieving its stated goals, including but not limited to preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management, under all potential future conditions, regardless of how remote.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

On October 15, 2021, the Company filed a lawsuit against Dr. Jamey Weichert, a former director and executive officer of the Company (“Dr. Weichert”) and Dr. Anatoly Pinchuk, a former employee and consultant of the Company (“Dr. Pinchuk”) in the U.S. District Court for the Western District of Wisconsin. The Company alleged, among other claims, that Dr. Weichert and Dr. Pinchuk breached their contractual and fiduciary duties to the Company by diverting intellectual property that rightfully belonged to the Company to a company controlled by Dr. Weichert. Although the disputed intellectual property does not directly affect the clinical studies of iopofosine or other compounds in the Company’s clinical pipeline, the disputed intellectual property may potentially enhance future areas of research, development, and commercialization. The Company was seeking monetary damages, injunctive relief, and reasonable attorneys’ fees and expenses in conjunction with the lawsuit. In November 2022, the Company announced that the Company, the Wisconsin Alumni Research Foundation, and Dr. Weichert and Dr. Pinchuk have resolved the lawsuit. All claims against Drs. Weichert and Pinchuk have been voluntarily dismissed, and the Company has secured an irrevocable, non-exclusive license to the patents at issue in the lawsuit.

Item 1A. Risk Factors

Other factors that could materially adversely affect our business and our equity securities are described in the Risk Factors previously disclosed in Form 10-K, our Annual Report filed with the SEC on March 9, 2023 pursuant to Section 13 or 15(d) of the Exchange Act. That information should be considered carefully, together with other information in this report and other reports and materials we file with the SEC.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

[Table of Contents](#)

Item 6. Exhibits

Exhibit No.	Description	Filed with this Form 10-Q	Incorporation by Reference		Exhibit No.
			Form	Filing Date	
3.1	Certificate of Elimination of the Series A Convertible Preferred Stock, the Series B Convertible Preferred Stock and the Series C Convertible Preferred Stock		8-K	September 8, 2023	3.1
3.2	Amendment No. 1 to Certificate of Designation of the Series D Preferred Stock		8-K	September 8, 2023	3.2
3.3	Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Voting Preferred Stock		8-K	September 8, 2023	3.3
3.4	Certificate of Amendment of Second Amended and Restated Certificate of Incorporation of Collectar Biosciences, Inc.		8-K	October 27, 2023	3.1
4.3	Form of Tranche A Warrant		8-K	September 8, 2023	4.3
4.4	Form of Tranche B Warrant		8-K	September 8, 2023	4.4
10.1	Form of Securities Purchase Agreement, dated September 5, 2023, by and among the Company and the purchasers named therein		8-K	September 8, 2023	10.1
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	Interactive Data Files	X			
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit).	X			

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CELLECTAR BIOSCIENCES, INC.

Date: November 13, 2023

By: /s/ James V. Caruso

James V. Caruso
President and Chief Executive Officer

I, JAMES V. CARUSO, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cellerar Biosciences, Inc., a Delaware Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ James V. Caruso

James V. Caruso

President and Chief Executive Officer

(Principal Executive Officer)

I, CHAD J. KOLEAN, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Collectar Biosciences, Inc., a Delaware Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2023

/s/ Chad J. Kolean

Chad J. Kolean

Chief Financial Officer

(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. § 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Collectar Biosciences, Inc. (the "Company") for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, James V. Caruso, President and Chief Executive Officer of the Company, and Chad J. Kolean, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge, that:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ James V. Caruso

James V. Caruso
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2023

/s/ Chad J. Kolean

Chad J. Kolean
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 13, 2023
